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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/515,283 02/29/00 AGHASSI N P-6335.01CIP

DANIEL D CHAPMAN
JACKSON WALKER LLP
112 E PECAN
SUITE 2100
SAN ANTONIO TX 78205

HM12/0530

EXAMINER

GRUN, J

ART UNIT

PAPER NUMBER

1641

DATE MAILED:

05/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/515,283

Applicant(s)
AGHASSI et al.

Examiner
James L. Grun, Ph.D.

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1641



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 Mar 2001
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-10, and 12-16 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-10, and 12-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

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To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1641.

The amendment filed 26 March 2001 is acknowledged and has been entered. Claims 7 and 11 have been cancelled. Claims 1-6, 8-10, and 12-16 remain in the case.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The amendment filed 26 March 2001 is objected to under 35 U.S.C. § 132 because it introduces new matter into the specification. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the addition to the end of the paragraph bridging pages 4-5 of the specification is not supported by the original disclosure as the specification teaches surfactants as emulsifiers or removing agents as part of a composition and not as performing, by itself, the function of the activating agent and also serving to enhance immunogenicity. Moreover, as set forth in the previous Office action there is no description or support for the general applicability of a recommended volume of a specific surfactant composition (SIMPLE GREEN®), having at least currently known concentrations of surfactants therein, as useful with unknown concentrations of other surfactants in the composition disclosed on page 11 of the specification also having therein citric acid and citrate salts.

Applicant is required to cancel the new matter in the response to this Office action.

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Claims 1-6, 8-10, and 12-16 are rejected under 35 U.S.C. 112, first paragraph, for the reasons of record that the specification contains subject matter which was not described in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, particularly the invention commensurate in scope with that as instantly claimed.

For the reasons of record, it remains unknown and entirely unpredictable, absent any description and guidance from Applicant, whether the components of the solution, by themselves, or the exemplified, and apparently essential, heating of the solution performs the functions of embedding medium removal and/or immunohistochemical staining/antigenicity enhancement. As set forth, absent further description and guidance from Applicant, one would not be assured of any predictable ability to formulate and provide a composition with such components for use in the methods with the properties as instantly claimed. Moreover, the providing of a desired goal for properties of a composition, and a listing of possible alternatives from which to perhaps formulate such a composition, is not seen as providing an enabling disclosure for those specific compositions which predictably function in the invention. Further, for the reasons of record, it remains unknown and entirely unclear and unpredictable that the suggested compositions function with anything other than aldehyde-fixed paraffin-embedded tissues. As set forth, function with,

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for example, alcohol-fixed tissue samples remains unknown in view of at least the teachings of Shi et al (J. Histochem. Cytochem. 39: 741-748, 1991).

Applicant's arguments filed 26 March 2001 have been fully considered but they are not deemed to be persuasive. Applicant urges that sufficient examples have been provided to enable the full breadth of the instant claims. This is not found persuasive for the reasons of record because the examples do not provide any evidence of paraffin embedding medium removal and/or immunohistochemical staining/antigenicity enhancement by the exemplified solutions in the absence of the required heat. Applicant urges that melting is not emulsification. This is not disputed. However, the argument remains unpersuasive because there is no evidence of emulsification in the absence of melting, the process which the Examiner submits produces the liquefied paraffin required for emulsifying. Applicant defines "emulsion" as a stable mixture of two or more immiscible **liquids**, which may require an elevated temperature for its maintenance (see e.g. page 8).

Claims 3 and 5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for addition of a 25% volume of SIMPLE GREEN® surfactant (see e.g. page 11), does not reasonably provide description and enablement generally for a 25% volume of surfactants.

Applicant's arguments filed 26 March 2001 have been fully considered but they are not deemed to be persuasive. Notwithstanding Applicant's assertion to the contrary, the amendment

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of the specification does not now conform to the invention as originally claimed as set forth previously in this Office action. For reasons of record, the concentration of surfactants can be adjusted in any stock solution and one would not know from the written description what surfactant concentrations were encompassed or not encompassed by the claims, other than a 25% volume of SIMPLE GREEN® surfactant which has a known current composition. One would not be assured of the ability to use another composition of indeterminate surfactant concentration in the invention as disclosed.

Claims 2, 4, 5, 8-10, and 13-15 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 4 contain the trademark/trade name SIMPLE GREEN®. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. In the present case, the trademark/trade name is used to identify/describe an aqueous surfactant solution containing, **by weight**, about 5.8% ethylene glycol monobutyl ether, about 3.75% nonylphenol ethoxylate, and about 1.5% tetrapotassium pyrophosphate (see e.g. U.S. Patent No. 5,856,289) and, accordingly, the identification/description is indefinite. The Examiner would note that the detergent compositions of claim 10 should likewise be specified.

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In claim 4, it is not clear what functions or components are encompassed by or in an "appropriate" buffer. In this claim, "a immunohistochemical" should be --an immunohistochemical--.

In claim 5, it is not clear what functions or components are encompassed by or in an "appropriate" buffer. In claim 5, "the" slide and tissue lack antecedent basis.

In claims 8-10, "the" aqueous emulsifying solution lacks antecedent basis and the interrelationships of the components are not clear.

In claim 9, it is not clear on what basis the percentage is determined.

In claims 13-14, "the...solution" lacks antecedent basis.

In claim 15, it is believed that --biodegradable-- was intended and it is not clear what is encompassed within the metes and bounds of the claim.

Applicant's arguments filed 26 March 2001 have been fully considered but they are not deemed to be persuasive. Notwithstanding Applicant's assertion to the contrary, the instant amendments have not obviated all of the issues under 35 U.S.C. § 112, second paragraph.

Claim 1 is rejected under 35 U.S.C. § 102(b) as being anticipated by Thorne (US 5,552,294), if necessary in light of Cattoretti et al (J. Pathol. 171: 83-98, 1993) and the instant disclosure for reasons of record. As set forth, recitations of intended use do not distinguish the prior art composition, having all of the components as instantly claimed which are inherently capable of performing the functions as disclosed and recited, from that as instantly claimed.

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Applicant's arguments filed 26 March 2001 have been fully considered but they are not deemed to be persuasive. Notwithstanding Applicant's assertion to the contrary, there is nothing of record to support that the instant language excludes an additional antibiotic component as used in the reference since "consisting essentially of" only excludes that which would materially change the character of the composition.

Applicant urges that the rejection over Thorne in light of the extrinsic evidence of inherency provided by the other cited references is not a rejection over a single reference. This is not found persuasive as extrinsic evidence of inherency is permissible in rejections under 35 U.S.C. § 102 and such evidence need not antedate the filing date. Applicant's attention is drawn to the discussion of "Multiple Reference 35 U.S.C. § 102 Rejections" in M.P.E.P. § 2131.01.

Claims 1, 3, 5, 6, 8-10, and 12-16 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the combined teachings of Hazelbag et al (J. Histochem. Cytochem. 43: 429-437, 1995), Shi et al (J. Histochem. Cytochem. 43: 193-201, 1995), and Yörükoğlu et al (Appl. Immunohistochem. 5: 71, 1997).

Claims 1, 3, 5, 6, 8-10, and 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hazelbag et al, Shi et al, and Yörükoğlu et al, and, if necessary, further in view of either of Norton et al (J. Pathol. 173: 371-9, 1994) or Miller et al (Applied Immunohistochem. 3: 190-3, 1995).

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Applicant's arguments filed 26 March 2001 have been fully considered but they are not deemed to be persuasive.

In response to Applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant urges that the references do not teach a single step process. This is not found persuasive for reasons of record, particularly in view of the unchallenged teachings of Yörükoğlu et al.

In response to Applicant's argument that the prior art does not teach detergent in the composition as emulsifier, the fact that Applicant has recognized another advantage which would flow naturally from following the suggestions of the combined prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Claim 3 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Ding et al.

Claim 3 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Prieto (U.S. SIR H1478).

Applicant's arguments filed 26 March 2001 have been fully considered but they are not deemed to be persuasive. In response to Applicant's argument that these references are nonanalogous art, it has been held that a prior art reference must either be in the field of

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applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the references are drawn to the subject matter of Applicant's claimed invention, a buffered aqueous surfactant composition. Note that a recitation of intended use is accorded patentable weight only to the extent that it limits the actual components of a composition; in the instant case the intended use does not affect the components in any way which distinguishes over the subject matter taught or suggested by the references.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A SHORTENED STATUTORY PERIOD FOR REPLY TO THIS FINAL ACTION IS SET TO EXPIRE **THREE MONTHS** FROM THE MAILING DATE OF THIS ACTION. IN THE EVENT A FIRST REPLY IS FILED WITHIN **TWO MONTHS** OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE **THREE-MONTH** SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR REPLY EXPIRE LATER THAN **SIX MONTHS** FROM THE MAILING DATE OF THIS FINAL ACTION.

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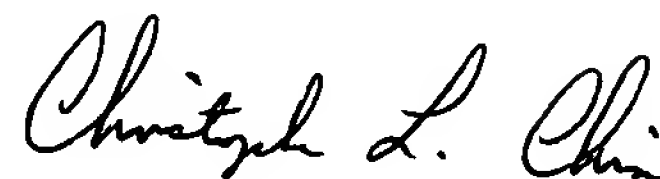
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to James L. Grun, Ph.D., whose telephone number is (703) 308-3980. The Examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Long Le, SPE, can be contacted at (703) 305-3399. The fax phone numbers for official communications to Group 1640 are (703) 305-3014 or (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



James L. Grun, Ph.D.
May 29, 2001



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641